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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/022,631

12/17/2001

Maurits W. Geerlings

2056-P01519US4

1753

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7590

09/23/2004

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EXAMINER

LUM, LEON YUN BON

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/022,631	<b>Applicant(s)</b> GEERLINGS, MAURITS W.	
	<b>Examiner</b> Leon Y Lum	<b>Art Unit</b> 1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 December 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 26-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 26-43 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 26-29, drawn to a method for killing target cells, classified in class 436, subclass 64.
  - II. Claims 30-38, drawn to a method for detecting a pathological site, classified in class 250, subclass 370.02.
  - III. Claims 39-43, drawn to a method for providing site directed radiotherapy, classified in class 436, subclass 7.2.
2. The inventions are distinct, each from the other because of the following reasons:
3. Inventions I and II are unrelated, independent, and distinct inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects. Group I is a method for killing target cells in a mammal, which is a different effect from Group II, which is a method for detecting a pathological site. Group I also includes the step of providing a sufficient quantity of <sup>225</sup>Ac to produce a therapeutically effective amount of

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$^{213}\text{Bi}$ , which is not a step in Group II. Group II also includes the step of detecting  $\alpha$ -particles emitted by said bound conjugate, which is not a step in Group I.

Therefore, Groups I and II have different modes of operation, different functions, and different effects that distinguish them as unrelated, independent, and distinct inventions.

4. Inventions I and III are unrelated, independent, and distinct inventions.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects. Group I is a method for killing target cells in a mammal, which is a different effect from Group III, which is a method for providing site directed radiotherapy to a pathological site. Group I also includes the step of providing a sufficient quantity of  $^{225}\text{Ac}$  to produce a therapeutically effective amount of  $^{213}\text{Bi}$ , which is not a step in Group III. Group III also includes the step of providing a radioconjugate of a targeting moiety bound indirectly to an  $\alpha$ -particle emitting radioisotope.

Therefore, Groups I and III have different modes of operation, different functions, and different effects that distinguish them as unrelated, independent, and distinct inventions.

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5. Inventions II and III are unrelated, independent, and distinct inventions.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects. Group II is a method for detecting a pathological site, which is a different effect from Group III, which is a method for providing site directed radiotherapy to a pathological site. Group II also includes the step of detecting  $\alpha$ -particles emitted by said bound conjugate, which is not a step in Group III. Group III also includes the step to produce a radiotherapeutic effect at said pathological site, which is not a step in Group II.

Therefore, Groups II and III have different modes of operation, different functions, and different effects that distinguish them as unrelated, independent, and distinct inventions.

6. Because these inventions are distinct for the reasons given above and the search required for each of Groups I-III is not required for the other Groups, restriction for examination purposes as indicated is proper. Group I requires a search in databases for target cells with specific dimensions, which is not a search required in Groups II-III. Group II requires a search for  $\alpha$ -particle detectors, which is a search for devices that is not required for Group I or III. Group III requires a search in databases for art that teaches radioconjugates which provide a radiotherapeutic effect, which is not a search required for Groups I-II.

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7. A telephone call was made to Patrick Hagan on 15 September 2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

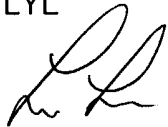
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LYL



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09/17/04